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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/005,760   | 11/12/2001  | Boaz Harari          | 687-456             | 1856             |
| 7590   | 06/01/2004  |                      | EXAMINER            |                  |
| JEFFREY J. HOHENHELL<br>AMERICAN MEDICAL SYSTEMS<br>10700 BREN ROAD WEST<br>MINNETONKA, MA 55343 |             |                      | PHILOGENE, PEDRO    |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3732                |                  |

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/005,760             | HARARI ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Pedro Philogene        | 3732                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 February 2004.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 10,11,15-23 and 25-27 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 23 and 25-27 is/are allowed.

6) Claim(s) 10,11 and 15-22 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/23/04.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

***Claim Objections***

Applicant is advised that should claim 16 be found allowable, claim 17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15,18,19,20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Romano (5,002,546).

With respect to claim 15, Romano discloses a self-aligning device for boring into bone comprising a boring head; as best seen in Fig.16, having at least two boring tips (61) a body, as seen in FIG.2, a handle attached to the body, as seen in FIG.1, a hinge, as seen in FIG.16, coupling the boring head to the body at a location substantially equidistant from the boring tips; as seen in FIGS.16, 18.

With respect to claims 18,19, Romano discloses all the limitations as best seen in FIGS.1-20.

With respect to claims 20-22, the method steps, as set forth, would have been inherently carried out in the operation of the device, as set forth above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romano (5,002,546) in view of Takasugi et al. (4,268,251).

With respect to claims 16,17, it is noted that Romano did not teach of tips comprising boring needle; as claimed by applicant. However, in a similar art, Takasugi et al evidence the use of a needle for boring a hole in a dental root canal.

Therefore, given the teaching of Takasugi et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Romano, as taught by Takasugi et al for boring a hole in a bone.

Claims 10,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisgaard (5,387,221) in view of Takasugi et al. (4,268,251).

With respect to claims 10 and 11, Bisgaard disclose at least one curved needle (12); a base (3) holding the handle and configured for being placed against a bone, a handle (10) coupled to the base, the handle capable of receiving a force in a particular direction for associating the device with a region that is at least substantially adjacent

bone; and a needle advancer (16), which advances the needle only when a force on the handle in a particular direction is higher than a predetermined amount, the predetermined amount assuring that the base is urged against the bone.

It is noted that Bisgaard did not teach of a bone boring needle, as claimed by applicant. However, in a similar art, Takasugi et al evidence the use of a needle for boring a hole in a dental root canal.

Therefore, given the teaching of Takasugi et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Bisgaard, as taught by Takasugi et al for boring a hole in a bone.

***Allowable Subject Matter***

Claims 23-27 are allowed.

***Response to Amendment***

Applicant's arguments, see pages 5-8 of the remarks, filed 2/23/04, with respect to the rejection(s) of claim(s) 10,11, 15-22 under 102(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Romano/Bisgaard.

Furthermore, during the interview on January 21, 2004, applicant was advised that three distinct inventions were being claimed in the application; and, applicant was given the option to choose one of the inventions for prosecution. Applicant is advised that before this application is passed to issue a restriction may be forth coming, if applicant did not select one of the inventions for prosecution.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene  
May 26, 2004



PEDRO PHILogene  
PRIMARY EXAMINER